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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/075,715 | 02/13/2002 | Michael Chopp | 1059,000 | 9739 |

7590 10/20/2003

KOHN & ASSOCIATES
Suite 410
30500 Northwestern Highway
Farmington Hills, MI 48334

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| EXAMINER |
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JAGOE, DONNA A

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 10/20/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,715

Applicant(s)

CHOPP ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 1-8 are pending in this application.

Response to Amendment

Objection of claims 7 and 8 is no longer maintained in view of the amendment.

Rejection of claim 5 under 35 U.S.C. §112 2nd paragraph is no longer maintained in view of the amendment.

Response to Arguments

Applicant's arguments filed July 18, 2003 have been fully considered but they are not persuasive.

1. The rejection made in paper number 4 over Moskowitz '940 under 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant asserts that while the therapeutic approach of Moskowitz is the reduction of cerebral infarction by lack of blood flow in the brain, the instant application induces brain remodeling and restoring neurological function. The examiner is not in agreement with this assertion. The action of the nitric oxide donor would inherently restore neurologic function in addition to increasing the blood flow to reduce the size of the infarct. If applicant is getting results that differ from the prior art by administering the same compound to the same population, it must be due to some limitation that is not in the claims. Regarding the timing of the administration of the compositions of Moskowitz, it is stated that the compounds can be administered before, during or after a

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stroke. Additionally, applicant asserts that the compounds of the instant application are drawn to methods of remodeling and restoring neurological function independent of the volume of the infarction. On page 5, lines 20-25 of the instant application, applicant defines "promoting neurogenesis" as neural growth being promoted or enhanced. This includes new neuronal growth, enhanced growth of existing neurons as well as growth and proliferation of parenchymal cells and cells that promote tissue plasticity. The following is a definition for parenchyma from Stedman's medical dictionary:

1. The distinguishing or specific cells of a gland or organ, contained in and supported by the connective tissue framework, or stroma. 2. The endoplasm of a protozoan cell. [G. anything poured in beside, fr. parencheo, 1 to pour in beside] p. glandulae thyroideae [TA] SYN: p. of thyroid gland. p. prostatae [TA] SYN: p. of prostate. p. of prostate [TA] the basic cellular tissue (substance) composing the prostate. SYN: p. prostatae [TA] . p. testis [TA] SYN: p. of testis. p. of testis [TA] the basic cellular tissue substance composing the testis, consisting of the seminiferous tubules and interstitial cells (Leydig and Sertoli cells) located within the lobules. SYN: p. testis [TA] . p. of thyroid gland [TA] the basic

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cellular tissue (substance) composing the thyroid
gland, organized as follicles. SYN: p. glandulae
thyroideae

It appears that applicant's definition for promoting neurogenesis does not necessarily mean neurogenesis, but rather proliferation of parenchymal cells that are not neurons.

Regardless, applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, the claims are directed to preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the

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instant application, applicants' failure to distance the proffered claims from the anticipated prophylactic utility renders such claims anticipated by the prior inherent use.

2. The rejection made in paper number 4 over Liao under 35 U.S.C. §102(e) is maintained and is hereby repeated. Applicant's Markush group of compounds includes atorvastatin, which is an HMG-CoA reductase inhibitor. Liao teaches HMG-CoA reductase inhibitors as upregulators of endothelial cell Nitric Oxide Synthase (Nitric Oxide donors). Regarding measurement of neurological function, since the instant application teaches that proliferation of parenchymal cells and cells that promote tissue plasticity are encompassed by the term "promote neurological function" measurement of neurological function is not necessary. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, the claims are directed to preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As

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often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA, 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility renders such claims anticipated by the prior inherent use.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

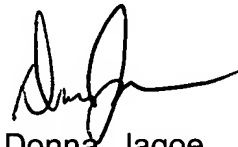
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-

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5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

